

ORIGINAL
CIVIL COVER SHEET

JS 44 - CAND (Rev. 11/04)

The JS-44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON PAGE TWO.)

I. (a) PLAINTIFFS

MARTHA ARRIOLA

DEFENDANTS

SMITHKLINE BEECHAM CORPORATION d/b/a
GLAXOSMITHKLINE(b) COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF NEVADA
(EXCEPT IN U.S. PLAINTIFF CASES)COUNTY OF RESIDENCE OF FIRST LISTED DEFENDANT Philadelphia, PA
(IN U.S. PLAINTIFF CASES ONLY)NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE
TRACT OF LAND INVOLVED.

(c) ATTORNEYS (FIRM NAME, ADDRESS, AND TELEPHONE NUMBER)

Nancy Herish, Esq.
Herish & Herish
601 Van Ness Avenue, Suite 2080
San Francisco, CA 94102
(415) 441-5544

ATTORNEYS (IF KNOWN)

Donald F. Zimmer, Esq.
Krista L. Cosner, Esq.
Drinker Biddle & Reath
50 Fremont St., 20th Floor
San Francisco, CA 94105

II. BASIS OF JURISDICTION (PLACE AN 'X' IN ONE BOX ONLY)

- ☐ 1 U.S. Government Plaintiff
☒ 2 U.S. Government Defendant
☒ 3 Federal Question (U.S. Government Not a Party)
☒ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (PLACE AN 'X' IN ONE BOX FOR PLAINTIFF AND ONE BOX FOR DEFENDANT)

- | | PTF | DEF | | PTF | DEF |
|---|---------------------------------------|----------------------------|---|----------------------------|---------------------------------------|
| Citizen of This State | <input type="checkbox"/> 1 | <input type="checkbox"/> 1 | Incorporated or Principal Place of Business in This State | <input type="checkbox"/> 4 | <input checked="" type="checkbox"/> 4 |
| Citizen of Another State | <input checked="" type="checkbox"/> 2 | <input type="checkbox"/> 2 | Incorporated and Principal Place of Business in Another State | <input type="checkbox"/> 5 | <input checked="" type="checkbox"/> 5 |
| Citizen or Subject of a Foreign Country | <input type="checkbox"/> 3 | <input type="checkbox"/> 3 | Foreign Nation | <input type="checkbox"/> 6 | <input type="checkbox"/> 6 |

IV. ORIGIN

(PLACE AN "X" IN ONE BOX ONLY)

- ☐ 1 Original Proceeding
☒ 2 Removed from State Court
☐ 3 Remanded from Appellate Court
☐ 4 Reinstated or Reopened
☐ 5 Transferred from Another district (specify)
☐ 6 Multidistrict Litigation
☐ 7 Appeal to District Judge from Magistrate Judgment

V. NATURE OF SUIT (PLACE AN "X" IN ONE BOX ONLY)

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 161 Medicare Act <input type="checkbox"/> 162 Recovery of Defaulted Student Loans (Excl Veterans) <input type="checkbox"/> 163 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	PERSONAL INJURY <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault Libel & Slander <input type="checkbox"/> 330 Federal Employers Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 360 Motor Vehicle <input type="checkbox"/> 365 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury PERSONAL INJURY <input checked="" type="checkbox"/> 362 Personal Injury <input checked="" type="checkbox"/> 365 Personal Injury Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability PERSONAL PROPERTY <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 610 Agriculture <input type="checkbox"/> 620 Other Food & Drug <input type="checkbox"/> 626 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 630 Liquor Laws <input type="checkbox"/> 640 RR & Truck <input type="checkbox"/> 650 Airline Regs <input type="checkbox"/> 660 Occupational Safety/Health <input type="checkbox"/> 690 Other LABOR <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Mgmt Relations <input type="checkbox"/> 730 Labor/Mgmt Reporting & Disclosure Act <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Empl. Ret. Inc. Security Act	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 PROPERTY RIGHTS <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 840 Trademark SOCIAL SECURITY <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) FEDERAL TAX SUITS <input type="checkbox"/> 870 Taxes (US Plaintiff or Defendant) <input type="checkbox"/> 871 IRS - Third Party 26 USC 7609	<input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce/ICC Rates/etc. <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Satellite TV <input type="checkbox"/> 810 Selective Service <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 875 Customer Challenge 12 USC 3410 <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 892 Economic Stabilization Act <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 894 Energy Allocation Act <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 900 Appeal of Fee Determination Under Equal Access to Justice <input type="checkbox"/> 950 Constitutionality of State Statutes <input type="checkbox"/> 890 Other Statutory Actions
REAL PROPERTY <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	CIVIL RIGHTS <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing <input type="checkbox"/> 444 Welfare <input type="checkbox"/> 440 Other Civil Rights <input type="checkbox"/> 445 Amer w/ disab - Empl <input type="checkbox"/> 446 Amer w/ disab - Other	PRISONER PETITIONS <input type="checkbox"/> 510 Motion to Vacate Sentence <input type="checkbox"/> Habeas Corpus: <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition		

VI. CAUSE OF ACTION (CITE THE US CIVIL STATUTE UNDER WHICH YOU ARE FILING AND WRITE BRIEF STATEMENT OF CAUSE. DO NOT CITE JURISDICTIONAL STATUTES UNLESS DIVERSITY)

28 U.S.C Section 1332

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION DEMAND \$ See below
UNDER F.R.C.P. 23 In excess of jurisdictional amount.

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ YES ☐ NO

VIII. RELATED CASE(S) IF ANY

PLEASE REFER TO CIVIL L.R. 3-12 CONCERNING REQUIREMENT TO FILE
"NOTICE OF RELATED CASE".

IX. DIVISIONAL ASSIGNMENT (CIVIL L.R. 3-2)

(PLACE AN "X" IN ONE BOX ONLY)

☒ SAN FRANCISCO/OAKLAND ☐ SAN JOSE

DATE MARCH 24 2008

SIGNATURE OF ATTORNEY OF RECORD Krista L. Cosner

ORIGINAL

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Attorneys for Defendant
 SMITHKLINE BEECHAM CORPORATION dba
 GLAXOSMITHKLINE

UNITED STATES DISTRICT COURT
 NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

MARTHA ARRIOLA,

Plaintiff,

v.

SMITHKLINE BEECHAM
 CORPORATION dba
 GLAXOSMITHKLINE; McKESSON
 CORPORATION; and DOES 1 through 15,
 inclusive,

Defendants.

Case No.

**NOTICE OF REMOVAL AND
 REMOVAL ACTION UNDER 28 U.S.C.
 § 1441(B) (DIVERSITY) and 28 U.S.C. §
 1441(C) (FEDERAL QUESTION) OF
 DEFENDANT SMITHKLINE
 BEECHAM CORPORATION d/b/a
 GLAXOSMITHKLINE**

TO THE CLERK OF THE COURT:

Defendant Smithkline Beecham Corporation dba GlaxoSmithKline ("GSK"), hereby removes to this court the state action described below. Removal is warranted under 28 U.S.C. § 1441 because this is an action over which this Court has original jurisdiction under 28 U.S.C. §§ 1331 and 1332.

I. BACKGROUND

1. On March 17, 2008, Plaintiff Martha Arriola ("Plaintiff"), represented by Hersh & Hersh of San Francisco, California, commenced this action in the Superior Court of the State of California for the County of San Francisco. A true and correct copy

1 of the Complaint in the action is attached as Exhibit "A " to the Declaration of Krista L.
2 Cosner in Support of Notice of Removal and Removal Action under 28 U.S.C. § 1441(b)
3 (Diversity) and 28 U.S.C. § 1441(c) (Federal Question) of Defendant SmithKline
4 Beecham Corporation dba GlaxoSmithKline (hereinafter "Cosner Decl.")).

5 2. Neither defendant has been served with Plaintiff's Complaint.

6 3. Defendant GSK filed its answer to the Plaintiff's Complaint on March 21,
7 2008. A true and correct copy of the Answer in the action is attached as Exhibit "B " to
8 Cosner Decl. There have been no additional proceedings in the state court action.
9 Cosner Decl. ¶ 2.

10 4. This is one of many cases that have been filed recently in both federal and
11 state court across the country involving the prescription drug Avandia®. Cosner Decl. ¶
12 6.

13 5. On October 16, 2007, the Judicial Panel on Multidistrict Litigation
14 ("JPML") issued an order directing that then-pending Avandia-related cases be
15 transferred and coordinated for pretrial proceedings in the United States District Court for
16 the Eastern District of Pennsylvania, before the Honorable Cynthia M. Rufe, pursuant to
17 28 U.S.C. § 1407. *See* Transfer Order, *In re Avandia Marketing, Sales Practices and*
18 *Products Liability Litigation*, MDL 1871 (E.D. Pa.) (a true and correct copy of which is
19 attached as Exhibit "C" to Cosner Decl.). Additional Avandia-related cases pending in
20 federal court, which are common to the actions previously transferred to the Eastern
21 District of Pennsylvania and assigned to Judge Rufe, are treated as potential tag-along
22 actions. *See id.*; *see also* Rules 7.4 and 7.5, R.P.J.P.M.L. 199 F.R.D. 425, 435-36 (2001).
23 GSK intends to seek the transfer of this action to that Multidistrict Litigation, *In re*
24 *Avandia Marketing, Sales Practices and Products Liability Litigation*, MDL 1871, and
25 shortly will provide the JPML with notice of this action pursuant to the procedure for
26 "tag along" actions set forth in the rules of the JPML. Cosner Decl. ¶ 7.

27 6. As more fully set forth below, this case is properly removed to this Court
28 pursuant to 28 U.S.C. § 1441 because GSK has satisfied the procedural requirements for

1 removal and this Court has subject matter jurisdiction over this action pursuant to 28
2 U.S.C. §§ 1331 and 1332.

3 **II. DIVERSITY JURISDICTION**

4 7. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332
5 because this is a civil action in which the amount in controversy exceeds the sum of
6 \$75,000, exclusive of costs and interest, and is between citizens of different states.

7 **A. Diversity Of Citizenship**

8 8. Plaintiff, Martha Arriola alleges she is a resident of the State of Nevada.
9 Accordingly, she is a citizen of the State of Nevada. *See* Cosner Decl., Exh. A, ¶ 2.

10 9. GSK is, and was at the time Plaintiff commenced this action, a corporation
11 organized under the laws of the Commonwealth of Pennsylvania with its principal place
12 of business in Philadelphia, Pennsylvania, and therefore, is a citizen of Pennsylvania for
13 purposes of determining diversity. 28 U.S.C. § 1332(c)(1). Cosner Decl. ¶ 8.

14 10. For the reasons set forth below, the remaining named defendant –
15 McKesson Corporation, a Delaware corporation, with its principal place of business in
16 San Francisco, California – has not been “properly joined and served,” and is otherwise
17 fraudulently joined. *See* Cosner Decl. ¶ 10. Therefore, its citizenship must be ignored
18 for the purpose of determining the propriety of removal. *See McCabe v. General Foods*,
19 811 F.2d 1336, 1339 (9th Cir. 1987); *Waldon v. Novartis Pharmaceuticals Corp.*, 2007
20 U.S. Dist. LEXIS 45809 (N.D. Cal. June 18, 2007).

21 **B. The Amount In Controversy Requirement Is Satisfied**

22 11. It is apparent on the face of the Complaint that Plaintiff seeks an amount in
23 controversy in excess of \$75,000, exclusive of costs and interest.

24 12. Plaintiff alleges that, as a result of her Avandia use, she “suffered chest pain
25 and stroke resulting in permanent damage to her vision.” *See* Cosner Dec. Exh. A, ¶ 27.

26 13. Plaintiff seeks to recover general damages; medical, hospital, and incidental
27 expenses; amounts for loss of earnings and loss of earning capacity, as well as punitive
28 and exemplary damages. *See* Exh. A, Prayer for Relief.

14. Punitive damages are included in the calculation of the amount in controversy. *See Bell v. Preferred Life Assurance Society*, 320 U.S. 238, 240 (1943).

15. Given the allegations set forth above, the face of the Complaint makes clear that Plaintiff seeks an excess of \$75,000, exclusive of interest and costs. *See Simmons v. PCR Tech.*, 209 F. Supp. 2d 1029, 1031 (N.D. Cal. 2002).

C. The Citizenship of McKesson Must Be Ignored Because McKesson Has Not Been Properly Joined and Served

16. Under 28 U.S.C. § 1441(b), an action is removable only if none of the parties in interest, *properly joined and served* as defendants, is a citizen of the State in which such action is brought. 28 U.S.C. § 1441(b) (emphasis added).

17. McKesson, although a citizen of California, has not yet been served with the Complaint in this case. Cosner Decl., ¶ 10.

18. Accordingly, because there is complete diversity of citizenship and because no “properly joined and served defendant” is a citizen of this State, it is appropriate that this action be removed to this Court. *See Waldon v. Novartis Pharmaceuticals Corp.*, 2007 U.S. Dist. LEXIS 45809 (N.D. Cal. June 18, 2007); *see also* 28 U.S.C. § 1441(b).

D. The Citizenship Of McKesson Must Be Ignored Because McKesson Is Fraudulently Joined

19. A defendant is fraudulently joined, and its presence in the lawsuit is ignored for purposes of determining diversity, “if the plaintiff fails to state a cause of action against the resident defendant, and the failure is obvious according to the settled rules of the state.” *Morris v. Princess Cruises, Inc.*, 236 F.3d 1061, 1067 (9th Cir. 2001); *see also Hamilton Materials, Inc. v. Dow Chemical Corporation*, 494 F.3d. 1203, 1206, 2007 WL 2080179 at *1 (9th Cir. 2007).

20. McKesson is fraudulently joined because Plaintiff has failed to make any material allegations against it. *See Brown v. Allstate Ins. Co.*, 17 F. Supp. 2d 1134, 1137 (S.D. Cal. 1998) (finding in-state defendants fraudulently joined where “no material allegations against [the in-state defendants] are made”).

21. In the body of the Complaint, Plaintiff asserts claims of: (1) strict products

liability – failure to warn; (2) negligence; (3) breach of implied warranty; (4) breach of express warranty; (5) fraud; (6) fraud by concealment; (7) negligent misrepresentation; and (8) violations of the Consumer Legal Remedies Act, Civil Code §1750, *et seq.* In these allegations, Plaintiff avers that collectively, “Defendants,” defectively designed and manufactured Avandia and made misrepresentations about the drug, Cosner Decl., Exh. A, at ¶¶ 22, 26, 37; failed to adequately and properly test and inspect Avandia, *id.* at ¶ 33; failed to use reasonable care in the labeling, selling, inspecting, packaging, and displaying of Avandia, *id.* at ¶ 33; and concealed known risks and failed to provide adequate warnings and labeling, *id.* at ¶¶ 26, 54-55.

22. With respect to McKesson, Plaintiff’s only allegation is that McKesson is, and was, engaged in the business of marketing, distributing, promoting, advertising and selling Avandia....” *Id.* at ¶ 5. Plaintiff cannot cure this deficiency by relying, as she does in the balance of her complaint, on allegations directed towards “Defendants.”

23. Plaintiff’s claims are substantively based on the design and manufacture of Avandia, the adequacy of pre-clinical testing and post-marketing surveillance, failure to warn, fraudulent concealment, and misrepresentation. As a wholesale distributor of Avandia, McKesson played no role whatsoever in its promotion, marketing or advertising. All McKesson did was pass along unopened boxes of Avandia, in unadulterated form, to hospitals and other businesses in the healthcare industry. *See* Declaration of Greg Yonko In Support of Defendant’s Notice of Removal and Removal Action Under 28 U.S.C. § 1441(b) (Diversity) and 28 U.S.C. § 1441(c) (Federal Question) in *F.C. Mitchell, et al. v. GlaxoSmithKline, et al.*, attached as Exhibit “D” to Cosner Decl., ¶¶ 6-7.¹

¹ The Declaration of McKesson’s representative, Greg Yonko may be considered by the Court in determining whether McKesson is fraudulently joined. *Maffei v. Allstate California Ins. Co.*, 412 F. Supp. 2d 1049 (E.D. Cal. 2006) (“[t]he court may pierce the pleadings, consider the entire record, and determine the basis of joinder by any means available”) (citing *Lewis v. Time, Inc.*, 83 F.R.D. 455 (E.D. Cal. 1979) (“it is well settled that upon allegations of fraudulent joinder...federal courts may look beyond the pleadings to determine if the joinder...is a sham or fraudulent device to prevent removal”)); *see also Ritchey v. Upjohn Drug Co.*, 139 F.3d 1313, 1318-19 (9th Cir. 1998) (evidence may be presented by the

24. Further, based on the “learned intermediary” doctrine, McKesson bore no duty to warn Plaintiff. The “learned intermediary” doctrine, the foundation of prescription drug product liability law, provides that the duty to warn about a drug’s risks runs from the manufacturer to the physician (the “learned intermediary”), and then from the physician to the patient. *See Brown v. Superior Court (Abbott Labs.)*, 44 Cal. 3d 1049, 1061-62, n.9 (1988); *Carlin v. Superior Court (Upjohn Co.)*, 13 Cal. 4th 1104, 1116 (1996). It is the physician, and only the physician, who is charged with prescribing the appropriate drug and communicating the relevant risks to the patient. *See Brown*, 44 Cal. 3d at 1061-62.

25. GSK and the FDA prepared the information to be included with the prescription drug, Avandia, with the FDA having final approval of the information that could be presented. Once the FDA has determined the form and content of the information, it is a violation of federal law to augment the information. *See* 21 U.S.C. § 331(k) (prohibiting drug manufacturers and distributors from causing the “alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling” of an FDA-approved drug held for sale); *Brown v. Superior Court*, 44 Cal. 3d 1049, 1069 n.12 (noting that the FDA regulates the testing, manufacturing, and marketing of drugs, including the content of their warning labels). Therefore, any safety and warning information McKesson had about Avandia would have come from GSK in the form of FDA-approved packaging and labeling. McKesson could not change the labeling it was given by GSK as approved by the FDA without violating federal law. No duty can be found where it requires a party to violate the law to fulfill it.

26. As such, given the lack of a causal connection between the injuries alleged by Plaintiff and McKesson’s conduct, as well as the absence of any legal or factual basis for Plaintiff’s claims against McKesson, McKesson’s joinder is fraudulent and its citizenship should be ignored for purposes of determining the propriety of removal.

removing party that there is no factual basis for the claims pleaded against the local defendant).

1 **III. FEDERAL QUESTION JURISDICTION**

2 27. This Court has federal question jurisdiction over Plaintiff's claims under 28
3 U.S.C. § 1331 and the principles set forth in *Grable & Sons Metal Prods., Inc. v. Darue*
4 *Eng'g & Mfg.*, 125 S. Ct. 2363 (2005).

5 28. As more fully explained below, Plaintiff has made violations of federal law
6 critical elements of several of her claims.

7 **A. Plaintiff's Claims Require Construction and Application of the FDCA** 8 **and Its Implementing Regulations**

9 29. Plaintiff's First Cause of Action, "Strict Products Liability – Failure to
10 Warn," Second Cause of Action, "Negligence," Fourth Cause of Action, "Breach of
11 Express Warranty," and Seventh Cause of Action, "Negligent Misrepresentation," each
12 require construction and application of the Federal Food, Drug and Cosmetic Act
13 ("FDCA") and implementing federal regulations, which govern approval of prescription
14 drugs and regulate prescription drug manufacturers' public and promotional statements,
15 including all aspects of warnings and labeling. *See* Cosner Decl., Exh. A.

16 30. As a currently-marketed prescription drug, Avandia is subject to extensive
17 regulation by the FDA. The FDCA requires the FDA to ensure that "drugs are safe and
18 effective" for their intended uses, 21 U.S.C. § 393(b)(2)(B), in part by "promptly and
19 officially reviewing clinical research and taking appropriate action on the marketing of
20 regulated products." 21 U.S.C. § 393(b)(1). The Secretary of the FDA has the authority
21 to promulgate regulations to enforce the FDCA, which are codified in the *Code of*
22 *Federal Regulations*, 21 C.F.R. § 200, *et seq.* *See* 21 U.S.C. § 371(a).

23 31. To accomplish its purpose, the FDA maintains a Center for Drug
24 Evaluation and Research (the "CDER"). The CDER regulates pharmaceutical
25 companies' development, testing and research, and manufacture of drugs. The CDER
26 examines data generated by these companies to conduct a risk/benefit analysis and make
27 an approval decision. The CDER also ensures truthful advertising for prescription drugs,
28 in part by approving Package Inserts that properly outline benefit and risk information.

1 Once drugs are marketed, the CDER continues to monitor them for unexpected health
 2 risks that may require public notification, a change in labeling, or removal of the product
 3 from the market. In short, the CDER evaluates and monitors the effectiveness and safety
 4 of prescription drugs. *See* <http://www.fda.gov/cder/about/faq/default.htm>.

5 32. Promotional communications to physicians about Avandia are contained
 6 within, and restricted by, warning, labeling, and promotional materials, such as the
 7 Package Insert, that are approved and monitored by the FDA to ensure the provision of
 8 accurate information about the drug's respective risks and benefits. Under federal
 9 regulations, even claims in promotional labeling or advertising must be consistent with
 10 approved labeling. 21 C.F.R. § 202.1(e)(4) (2005).

11 33. The FDA's responsibility to regulate prescription drugs sold in the United
 12 States, and to enforce laws with respect to such drugs, inclusive of the precise content
 13 and format of prescription drug labeling (*e.g.*, the instructions, warning, precautions,
 14 adverse reaction information provided by manufacturers, and marketing materials), is
 15 plenary and exclusive. *See* 21 U.S.C. § 301, *et seq.*

16 34. Plaintiff has made alleged violations of federal law a critical element of her
 17 claims. Accordingly, Plaintiff's claims necessarily raise substantial federal questions by
 18 requiring the Court to construe and apply the FDCA and its implementing regulations.

19 **B. Federal Control of Drug Labeling and Warning**

20 35. On January 24, 2006, the FDA announced a rule that includes a detailed
 21 and emphatic statement of the FDA's intention that its regulation and approval of
 22 prescription drug labeling preempt most state law claims related to the adequacy of
 23 prescription drug warnings because such claims frustrate "the full objectives of the
 24 Federal law." *See* Requirements on Content and Format of Labeling for Human
 25 Prescription Drug and Biologic Products, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006) ("FDA
 26 believes that under existing preemption principles, FDA approval of labeling under the
 27 act. . . . preempts conflicting or contrary State law."); *see also In re Bextra and Celebrex*
 28 *Marketing*, 2006 WL 2374742 (N.D. Cal. Aug. 16, 2006) (Celebrex decision); *In re*

1 *Bextra and Celebrex Marketing*, 2006 WL 2472484 (N.D. Cal. Aug. 24, 2006) (Bextra
2 decision).

3 36. Plaintiff alleges that Defendants failed to disclose certain risks of Avandia.
4 *See e.g.*, Cosner Decl. Exh. A, ¶ 16. This allegation necessarily requires Plaintiff to
5 establish that the FDA, which has exclusive jurisdiction over the labeling of drugs, would
6 have approved the warning the Plaintiff alleges should have been given.

7 37. Accordingly, there is a substantial federal question with respect to whether
8 Plaintiff can claim that GSK violated state law in light of the FDA's control of Avandia's
9 labeling and warning and its position on conflict preemption.

10 **C. The Federal Interest In Providing A Forum**

11 38. The federal government has a strong interest in having a federal court
12 decide several of the issues in this case. Among these issues are:

- 13 a. whether any conduct of GSK violated any federal laws or
14 regulations related to the labeling and marketing of Avandia; and
15 b. whether the FDA-approved Avandia label was false and misleading,
16 as alleged by Plaintiff, and whether a state may impose liability on
17 GSK for not providing more information regarding alleged risks, as
18 Plaintiff contends GSK should have done.

19 39. Plaintiff's claims may be vindicated or defeated only by construction of
20 federal statutes and regulations. The availability of a federal forum to protect the
21 important federal interests at issue is therefore consistent with *Grable*, and determination
22 by a federal court of the substantial and disputed federal issues that lie at the heart of this
23 case would not "disturb any congressionally approved balance of federal and state
24 judicial responsibilities." *Grable*, 125 S. Ct. at 2368.

25 **IV. CONFORMANCE WITH PROCEDURAL REQUIREMENTS**

26 40. This Court has jurisdiction over this matter based on federal question and
27 diversity of citizenship, and the present lawsuit may be removed from the Superior Court
28 of the State of California for the County of San Francisco, and brought before the United

1 States District Court for the Northern District of California pursuant to 28 U.S.C. §§
2 1331, 1332 and 1441.

3 41. Neither GSK nor McKesson has been served with Plaintiff's Complaint.
4 See Cosner Decl. ¶¶ 9-10. Therefore, this Removal has been timely filed. See 28 U.S.C.
5 § 1446(b).

6 42. Since neither GSK nor McKesson has been "properly joined and served" at
7 the time of filing this Removal, GSK is entitled to removal under the plain language of 28
8 U.S.C. § 1441(b). See *Waldon v. Novartis Pharmaceuticals Corp.*, 2007 U.S. Dist.
9 LEXIS 45809 (N.D. Cal. June 18, 2007); see also 28 U.S.C. § 1441(b); Cosner Decl. ¶¶
10 9-10.

11 43. Moreover, McKesson's consent to remove is not necessary because it is
12 fraudulently joined. See, e.g., *Emrich v. Touche Ross & Co.*, 846 F.2d 1190, 1193 n.1
13 (9th Cir. 1988).

14 44. The United States District Court for the Northern District of California is
15 the federal judicial district encompassing the Superior Court of the State of California for
16 the County of San Francisco, where this suit was originally filed. Venue therefore is
17 proper in this district under 28 U.S.C. § 1441(a).

18 45. Pursuant to the provisions of 28 U.S.C § 1446(d), GSK will promptly file a
19 copy of this Notice of Removal with the clerk of the Superior Court of the State of
20 California for the County of San Francisco, where this suit was originally filed.

21 46. Defendant reserves the right to amend or supplement this Notice of
22 Removal.

23 ///

24 ///

25 ///

26 ///

27 ///

28 ///

1 **WHEREFORE**, GSK respectfully removes this action from the Superior Court of
2 the State of California for the County of San Francisco to the United States District Court
3 for the Northern District of California, pursuant to 28 U.S.C. § 1441.

4
5 Dated: March 24, 2008

DRINKER BIDDLE & REATH LLP

6 
7 DONALD F. ZIMMER, JR.
KRISTA L. COSNER

8 Attorneys for Defendant
9 SMITHKLINE BEECHAM
CORPORATION dba
10 GLAXOSMITHKLINE
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